CI-0012



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Shirley MIEKKA, Martin J. MACPHEE, William N. DROHAN, David M. MANN and Wilson BURGESS

Serial No.:

09/960,703

September 24, 2001

For:

Filed:

METHODS OF STERILIZING PREPARATIONS

OF NON-AQUEOUS SOLVENTS

: Group Art Unit: 1744

: Examiner: To be assigned

07.

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).
- 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Réjection OR Notice of Allowance OR an action that otherwise closes prosecution in the application 37 C.F.R. §1.97(c).

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- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(c)(1).
- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- c. Attached is our check no. _____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).
- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- <u>X</u> 4. The relevancy of the non-English language references can be determined from the attached abstracts.

Serial No. 09/960,703

5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted, FLESHNER & KIM, LLP

Correspondence Address: P.O. Box 221200 Chantilly, VA 20153-1200 Telephone: (703) 502-9440 Date:March 25, 2002

MLF:DRM:kpc

Donald R. McPhail Registration No. 35,811

Mark L. Fleshner Registration No. 34,596

ATTY. DOCKET NO. APPLN. SERIAL NO. CI-0012 09/960.703 F PRIOR ART CITED BY **APPLICANT APPLICANT** Shirl y MIEKKA tal. E (PTO-1449) FILING DATE **GROUP September 24, 2001** 1744 U.S. PATENT DOCUMENTS EXAMINER *ISSUE **FILING** INITIALS *PATENT NO. DATE *INVENTOR NAME CLASS **SUBCLASS** DATE RE 23,195 02/1950 Arno Brasch 2,832,689 04/1958 Bernard E. Proctor et al. 2,920,969 01/1960 E.S. Stoddard 2,962,380 11/1960 J.H. Wertheim 3,620,944 11/1971 Keiko Tanito 3,743,480 07/1973 John D. Falk 3,779,706 12/1973 Nablo 4,136,094 01/1979 Condie 4,251,437 02/1981 Rasmussen et al. 4,282,863 08/1981 Beigler et al. 4,330,626 05/1982 Blair et al. U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN. PUB. NO. *PUB. *APPLICANT **CLASS SUBCLASS** DATE **U.S. PATENT APPLICATIONS** *APPLN. *FILING NO. DATE *INVENTOR CLASS **SUBCLASS FOREIGN PATENT DOCUMENTS EXAMINER'S** Translation **INITIALS** PATENT NO. DATE COUNTRY **CLASS SUBCLASS** 2,056,619 10/1991 Canada 310 316 04/1989 Europe 334 679 09/1989 Europe 919 918 A2 06/1999 Europe (Abstract) X 919 918 A3 06/1999 Europe (Abstract) OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) AABB FDA Liaison Meeting, ABC Newsletter, December 12, 1997, pp. 14 Ozan Akkus et al., Fracture Resistance of Gamma Radiation Sterilized Cortical Bone Allografts, 2001, pps. 927-934, Journal of Orthopaedic Research, Vol. 19 Tikvah Alper et al., The Exceptionally Small Size of the Scrapie Agent, 1966, pps. 278-284, Biochemical and Biophysical Research Communications, Vol. 22, No. 3 **EXAMINER DATE CONSIDERED**



LIST OF PRIOR ART CITED BY

PE APPLICANT

ATTY. DOCKET NO.
CI-0012

APPLICANT
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Luis 2 5 200	(PTO-1449)			FILING DATE September 2	GROUP 1744			
Com		U	.S. PATENT DO	OCUMENTS	translage as a	·	-	
EXAMINATES	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME Kotitschke et al.		CLASS	SUBCLASS	FILI DA	
	4,370,264	01/1983						
	4,409,105	10/1983	Hayashi et al.					
	4,472,840	09/1984	Jefferies					
	4,620,908	11/1986	Van Duzer					_
	4,865,602	09/1989	Smestad et al.					
	4,933,145	06/1990	Uchida et al.					
	4,946,648	08/1990	Dichtelmüller e	et al.				
	4,963,356	10/1990	Calenoff et al.					
	5,000,951	03/1991	Bass et al.					
	5,106,619	04/1992	Wiesehahn et al.					
	5,134,295	07/1992	Wälischmiller					
	5,185,371	02/1993	Rubinstein					
		U.S. PATE	NT APPLICAT	ION PUBLICAT	IONS			
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT		CLASS	SUBCLASS		
	<u></u>	<u> </u>						
EXAMINER'S	1	T	OREIGN PATENT 	DOCUMENTS			Trans	lation
INITIALS	PATENT NO.	DATE	cc	UNTRY	CLASS	SUBCLASS	Yes	No
	11-216147	08/1999	Japan (Abstract)				X	
	1321420-A	07/1987	Soviet Union (Abstract)			X	
	WO 90/00907	02/1990	PCT Int'l (Abs	tract)			X	
	WO 91/16060	10/1991	PCT Int'l (Abstract)				X	
	WO 95/03071	02/1995	PCT Int'l (Abstract)				X	
OTH.	ER ART (Includi	ng Author, Ti	tle, Date, Pertin	ent Pages, Publis	sher, Place of	Publication, E	Etc.)	
1	Tikvah Alper et al., Protection by Anoxia of the Scrapie Agent and Some DNA and RNA Viruses							
	Irradiated as Dry Preparations, 1968, pps. 157-166, J. Gen. Virol., Vol. 3							
	Tikvah Alper et al., Does the Agent of Scrapie Replicate Without Nucleic Acid? May 20, 1967,							
	pps. 764-766, Na	ture, Vol. 214						
	Tikvah Alper et al., The Scrapie Agent: Evidence Against its Dependence For Replication on							
	Intrinsic Nucleic Acid, 1978, pps. 503-516, J. Gen. Virol., Vol. 41							
EXAMINER				ATE CONSIDERED				



ATTY. DOCKET NO. APPLN. SERIAL NO. CI-0012 09/960,703 LIST OF PRIOR ART CITED BY **APPLICANT APPLICANT** Shirl y MIEKKA tal. **FILING DATE GROUP** (PTO-1449) Sept mber 24, 2001 1744 U.S. PATENT DOCUMENTS **FILING** *ISSUE DATE *INVENTOR NAME **CLASS SUBCLASS** *PATENT NO. DATE Held et al. 5,226,065 07/1993 Kent 5,362,442 11/1994 Plat. et al. 5,418,130 05/1995 10/1995 Kemp 5,460,962 Sreebny et al. 04/1996 5,510,122 5,603,894 02/1997 Aikus et al. Shanbrom 5,609,864 03/1997 Ben-Hur et al. 06/1997 5,637,451 5,643,464 07/1997 Rhee et al. Horowitz et al. 5,712,086 01/1998 03/1998 Peterson 5,730,933 10/1998 Böhm et al. 5,817,528 U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN. **SUBCLASS** *APPLICANT CLASS PUB. NO. *PUB. DATE FOREIGN PATENT DOCUMENTS Translation **EXAMINER'S** CLASS **SUBCLASS** PATENT NO. **INITIALS** DATE COUNTRY Yes X WO 00/25839 PCT Int'l (Abstract) 03/2000 X 02/2001 PCT Int'l (Abstract) WO 01/08611A1 X PCT Int'l (Abstract) WO 01/12318A1 02/2001 Х PCT Int'l (Abstract) WO 01/32107A2 05/2001 PCT Int'l (Abstract) WO 01/32110A2 | 05/2001 OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) S.R. Aparicio et al., Light and Electron Microscopy Studies on Homograft and Heterograft Heart Valves, 1975, pps. 174-162, J. Path, Vol. 115 J. Baksa et al., The Use of Pig's Skin (xenograft) for the Treatment of Burns, 1976, pps. 138-145, Magyar Traumatologin, Vol. 19 Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 10-78, American Association of Blood Banks DATE CONSIDERED **EXAMINER**



ATTY, DOCKET NO. APPLN. SERIAL NO. CI-0012 09/960,703 F PRIOR ART CITED BY **APPLICANT** APPLICANT Shirley MIEKKA et al. FILING DATE **GROUP** (MAR 2 5 2002 & (PTO-1449) Sept mb r 24, 2001 1744 U.S. PATENT DOCUMENTS **FILING** EXAM *ISSUE DATE CLASS **SUBCLASS** *PATENT NO. DATE *INVENTOR NAME S INITIALS 11/1998 Ding et al. 5,837,313 03/1999 Ahlqvist et al. 5,881,534 5,981,163 11/1999 Horowitz et al. 11/1999 Noishiki 5,986,168 Burton et al. 6,046,024 04/2000 Stone et al. 6,049,025 04/2000 Yew et al. 6,066,626 05/2000 Margolis-Nunno et al. 6,087,141 07/2000 09/2000 Brault et al. 6,120,592 Deghenghi 6,159,490 12/2000 Kent 6,171,549 01/2001 U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN. CLASS **SUBCLASS** *APPLICANT PUB. NO. *PUB. DATE **U.S. PATENT APPLICATIONS** *APPLN. *FILING **SUBCLASS** CLASS *INVENTOR NO. DATE FOREIGN PATENT DOCUMENTS Translation **EXAMINER'S** SUBCLASS **CLASS** Yes COUNTRY INITIALS PATENT NO. DATE X PCT Int'l (Abstract) 06/2001 WO 01/45720A1 X PCT Int'l (Abstract) WO 01/49219A1 | 07/2001 X PCT Int'l (Abstract) WO 01/72233A1 | 10/2001 X PCT Int'l (Absrtact) 10/2001 WO 01/72244A1 Х WO 01/91818A1 | 12/2001 PCT Int'l (Abstract) OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) R.H. Bassin et al., Abrogation of Fv-1^bRestriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2 Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150 Sandra Blakeslee, Tight Rules on Use of Organs Do Not Apply to Tissues, January 20, 2002, The New York Times Newspaper DATE CONSIDERED **EXAMINER**



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APPLN. SERIAL NO. ATTY. DOCKET NO. CI-0012 09/960,703 F PRIOR ART CITED BY **APPLICANT APPLICANT** Shirley MIEKKA et al. **GROUP** FILING DATE F (PTO-1449) Septemb r 24, 2001 1744 U.S. PATENT DOCUMENTS **FILING** EXAM *ISSUE DATE *PATENT NO. DATE *INVENTOR NAME CLASS **SUBCLASS** INITIALS 02/2001 Platz et al. 6,187,572 6,190,855 02/2001 Herman et al. 6,197,207 03/2001 Chapman et al. 6,203,544 03/2001 Gotzen Horowitz et al. 6,214,534 04/2001 05/2001 Sowemimo-Coker et al. 6,235,508 Abraham 4,784,850 11/1998 Freeman, Jr. 4,798,611 01/1989 02/1994 Okrongly et al. 5,283,034 08/1996 Leneau et al. 5,548,066 11/1999 Odland 5,989,498 U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN. **CLASS SUBCLASS** PUB. NO. *PUB. *APPLICANT DATE **U.S. PATENT APPLICATIONS** *APPLN. *FILING **CLASS SUBCLASS** DATE *INVENTOR NO. FOREIGN PATENT DOCUMENTS Translation **EXAMINER'S SUBCLASS** CLASS PATENT NO. DATE COUNTRY **INITIALS** OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) Seymour S. Block, Disinfection, Sterilization, and Preservation, Fundamental Principles of Activity Principles of Antimicrobial Activity, Fourth Edition, 1991, pps. 31-33 A.J.J.C. Bogers et al., Long-Term Results of the Gamma-Irradiation-Preserved Homograft Monocusp for Transannular Reconstruction of the Right-Ventricular Outflow Tract in Tetralogy of Fallot, 1994, pps. 337-330, Thorac. Cardiovasc. Surgeon, Vol. 42 David R. Brown et al., Antioxidant Activity Related to Copper Binding of Native Prion Protein, 2001 pps. 69-76, Journal of Neurochemistry, Vol. 76 DATE CONSIDERED **EXAMINER**





APPLN. SERIAL NO. ATTY. DOCKET NO. CI-0012 09/960,703 🔀 PRIOR ART CITED BY **APPLICANT** APPLICANT Shirley MIEKKA tal. MAR 2 5 2002 3 FILING DATE **GROUP** &PTO-1449) September 24, 2001 1744 COMER ARTO Cluding Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) P. Brown, The Risk of Blood-Borne Creutzfeldt-Jakob Disease, 1999, pps. 53-59, Advances in Transfusion Safety Dev. Biol. Vol. 102 P. Brown et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, November/December 1999, pps. 1169-1178, Transfusion, Vol. 39 Paul Brown et al., Effect of Chemicals, Heat, and Histopathologic Processing on High-Infectivity Hamster-Adapted Scrapie Virus, May 1982, pps. 683-687, The Journal of Infectious Diseases, Vol. 145, No. 5 P. Brown et al., The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy, September 1998, pps. 810-816, Transfusion, Vol. 38 D.G. Campbell et al., Sterilization of HIV With Irradiation: Relevance to Infected Bone Allografts, 1999, pps. 517-521, Aust. N.Z.J. Surg., Vol. 69 Ernest U. Conrad et al., Transmission of the Hepatitis-C Virus by Tissue Transplantation, February 1995, pps. 214-224, The Journal of Bone and Joint Surgery, Vol. 77-A, No. 2 A.S. Dagli, Correction of Saddle Nose Deformities by Coral Implantation, 1997, pps. 274-276, Eur. Arch. Otorhinolaryngol, Vol. 254 Defeng et al., Sterilization of Silver-Acidum Pipemedicum Skin for the Treatment of Burns by Radioactive Cobalt-60-. Gamma. - Ray, 1995, pps. 406 (Abstract) P. Di Simplicio et al., The Reactivity of the SH Group of Bovine Serum Albumin With Free Radicals, 1991, pps. 253-262, Free Rad. Res. Comms., Vol. 14, No. 4 R.J. Donnelly et al., Gamma-radiation of Heart Valves at 4°C; A Comparative Study Using Techniques of Histochemistry and Electron and Light Microscopy, 1973, pps. 95-101, Thorax, Vol. 28 Duane C. Eichler et al., Radiation Inactivation Analysis of Enzymes, July 15, 1987, pps. 9433-9436, The Journal of Biological Chemistry, Vol. 262, No. 20 Luanne H. Elliott et al., Inactivation of Lassa, Marburg and Ebola Viruses by Gamma Irradiation, Q Oct. 1982, pps. 704-708, Journal of Clinical Microbiology, Vol. 16, No. 4 Bradley M. Fideler et al., Gamma Irradiation: Effects on Biomechanical Properties of Human Bone-Patellar Tendon-Bone Allografts, 1995, pps. 643-646, American Journal of Sports Medicine, Vol. 23, No. Bradley M. Fideler et al., Effects of Gamma Irradiation on the Human Immunodeficiency Virus, July 1994, The Journal of Bone and Joint Surgery, Vol. 76-A, No. 7 Fields et al., Susceptibility of Scrapie Agent to Ionizing Radiation, April 5, 1969, pps. 90-91, Nature, Vol. 222 M.M. Ghosh et al., A Comparison of Methodologies for the Preparation of Human Epidermal-Dermal Composites, October 1997, pps. 390-404, Annals of Plastic Surgery, Vol. 39, No. 4 J.R.P. Gibbons et al., Effects of Gamma Irradiation on the Initial Mechanical and Material Properties of Goat Bone-Patellar Tendon-Bone Allografts, 1991, pps. 209-218, J. Orthop Res, Vol. 9, No. 2 **DATE CONSIDERED** EXAMINER

CAPPLICANT MAR 2 5 2002		ATTY. DOCKET NO. CI-0012	APPLN. SERIAL NO. 09/960,703		
		APPLICANT Shirl y MIEKKA tal.			
MAR 2 5	PTO-1449)	FILING DATE S ptemb r 24, 2001	GROUP 1744		
ON ERABLE Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)					
	J.R.P. Gibbons et al., Gamma Ray Sterilisation of	of Homograft Valves, 1969, pps	s. 353-358, Bulletin De La		
	Societe Internationale De Chirugie, No. 3				
	M.J. Goertzen et al., Anterior Cruciate Ligament Reconstruction Using Cryopreserved Irradiated				
	Bone-ACL-Bone-Allograft Transplants, 1994, pps. 150-157, Knee Surgery Sports Traumatology Arthroscopy, Vol. 2 M.J. Goertzen et al., Sterilisation of Canine Anterior Cruciate Allografts by Gamma Irradiation in Argon, March 1995, pps. 205-212, The Journal of Bone and Joint Surgery, Vol. 77-B, No. 2 Slawomir Gregorczyn et al., Strength of Lyophilized and Irradiated Cortical Bone of the Human Femur,				
1					
	1995, pps. 129-133, Chir. Narz. Ruchu Ortop. Pol., Lx 2				
	D.A. Haig, Further Studies on the Inactivation of		let Light, 1969,		
4	pps. 455-457, J. Gen. Virol., Vol. 5				
	F.W. Hehrlein et al., Biochemische Veränderungen an Heterologen Aortenklappentransplantaten nach (English Summary found at p. 183)				
	Anwendung Verschiedener Sterilisationsverfahren, pps. 1183-1185, Langenbecks Arch. Chir., Bd. 325 (Kongrebericht)				
	F.W. Hehrlein et al., Morphologische Utersuchungen an Heterologen Herzklappentransplantaten Unter				
	Verschiedenen Sterilisationsbedingungen, pps. 2	244-251 (English Summary fou	nd at p. 250)		
	H. Hiemstra et al., Inactivation of Human Immunodeficiency Virus by Gamma Radiation and its Effect on				
	Plasma and Coagulation Factors, 1991, pps. 32-39, Transfusion, Vol. 31, No. 1				
	Richard Hinton et al., A Biomechanical Analysis of Solvent-dehydrated and Freeze-Dried Human Fascia Lata Allografts, 1992, pps. 607-612, The American Journal of Sports Medicine, Vol. 20, No. 5				
	B. Horowitz et al., Inactivation of Viruses in La				
	1985, pps. 523-527, Transfusion, Vol. 25, No. 6				
	M. Horowitz, Sterilization of Homograft Ossicl		nber 1979, pps. 1087-1089,		
	The Journal of Laryngology and Otology, Vol.		· · · · · · · · · · · · · · · · · · ·		
	Carol House et al., Inactivation of Viral Agents		radiation, 1990		
	pps. 737-740, Can. J. Microbiol., Vol. 36				
	Shinichiro Ijiri et al., Effect of Sterilization on I	Bone Morphogenetic Protein, 19	994, pps. 628-636,		
	Journal of Orthopaedic Research, Vol. 12				
	A.S. Imamaliev et al., Biological Properties of l	Bone Tisue Conserved in Plastic	c Material and Sterilized		
	With Gama Rays, 1974, pps. 129-135, ACTA, (
	A. Ingegneri et al., An 11-Year Assessment of 93 Flash-frozen Homograft Valves in the Aortic Position, 1979, pps. 304-307, Thorac. Cardiovasc. Surgeon, Vol. 27				
	J. Jerosch et al., A New Technique for Bone Ste		Biomedizinische		
	Technik, Band 34, Heft 5				
		Periods on the Stability and the Wa	ter Content of Bone Allografts		
	 J. Jerosch et al., Influence of Different Rehydration Periods on the Stability and the Water Content of Bone Allografts After Lyophilization, Gamma-Irradiation, and Lipid Extraction, 1994, pps. 335-341, Z. Orthop., Vol. 132 J.D. Keathley et al., Is There Life After Irradiation? Part 2: Gamma-Irradiated FBS in Cell Culture 				
	July/August 1993, pps. 46-52, BioPharm				
EXAMINER		DATE CONSIDERED			





LIST OF PRIOR ART CITE APPLICANT

ATTY. DOCKET NO. CI-0012

APPLN. SERIAL NO. 09/960,703

APPLICANT

Shirley MIEKKA tal.

Shirley MIEKKA tal.				
	(PTO-1449) (MAR 2 5 2002 3	FILING DATE S ptember 24, 2001	GROUP 1744	
OTHER ART (Including Author, Title Date, Page ent Pages, Publisher, Place of Publication, Etc.)				
E.S. Kempner et al., Size Determination of Enzymes by Radiation Inactivation, 1979, pps. 2-10, Analytical				
Biochemistry, Vol. 92				
	L. Kerboull et al., In Vitro Study of the Influence of Avrious Conservation Methods on the Mechanical Properties of Patellar Tendon Allografts, 1991, pps. 751-762, Chirurgie, Vol. 117 A.D. Kitchen, Effect of Gamma Irradiation on the Human Immunodeficiency Virus and Human Coagulation Proteins, 1989, pps. 223-229, Vox Sang, Vol. 56 Andrezej Komender et al., Some Biological Properties of Bovine Trypsinized Fascia Xenografts, 1981, pps. 485-489, Archivum Immunologiae et Therapiae Experimentalis, Vol. 29 Andrezej Komendar et al., Some Biological Properties of Preserved Bovine Fascia Enrighed With			
	Pulverized Calf Cartilage, 1984, pps. 211-219, Archivum Immunologiae et Therapiae Experimentalis, Vol. 32			
	J.F. Kouvalchouk et al., The Use of Sterilized Bo			
	1986, pps. 393-401, Revue de Chirurgie Orthope	dique, Vol. 72		
	Raymond Latarjet, Inactivation of the Agents of		ease, and Kuru by	
	Radiations, 1979, pps. 387-407, Slow Transmiss			
	R. Latarjet et al., Inactivation of the Scrapie Agent by Near Monochromatic Ultraviolet Light,			
	September 26, 1970, pps. 1341-1343, Nature, Vol. 227 Douglas C. Lee et al., A Direct Relationship Between the Partitioning of the Pathogenic Prion Protein and Transmissible Spongiform Encephalopathy Infectivity During the Purification of Plasma Proteins, April 2001, pps. 449-455, Transfusion, Vol. 41 Susan F. Leitman, Use of Blood Cell Irradiation in the Prevention of Posttransfusion Graft-vs-Host Disease, 1989, pps. 219-232, Transfus. Sci., Vol. 10			
	Linberg et al., Irradiated Homologous Cartilage For O	rbital Reconstruction, July 1980,	pps. 457-462,	
Ophthalmic Surgery, Vol. 11			•	
	Sandra McDowell, Irradiated Cartilage, Spring 1988, pps. 14-15, Plastic Surgical Nursing A. Maeda et al., Effects of Solvent Preservation With or Without Gamma Irradiation on the Material Proper			
	Canine Tendon Allografts, 1993, pps. 181-189, Journal			
<u> </u>	Akira Maeda et al., Solvent-dried and Gamma-irradiat	·		
	Journal of Bone and Joint Surgery, Vol. 80-B, No. 4	Se Tendon Amogratio in Rato, Jul	y 1220, pps. 131 130, 1110	
	S. Malawski et al., The Use of Dry-Freezed Bone Gra	fs Sterilized by Gamma Rays in C	Orthopaedic Surgery, 1969,	
	pps. 61-68, Chir. Narz. Ruchu Ortop.	, , , , , , , , , , , , , , , , , , , ,		
	Linda Marton et al., Disinfection and Inactivation of t	he Human T. Lymphotrogic Viru	s Type III/Lymphadenopathy-	
	Associated Virus, August 1985, pps. 499-403, The Journal of Infectious Diseases, Vol. 151, No. 2 S.I. Miekka et al., New Methods for Inactivation of Lipid-enveloped and Non-enveloped Viruses, 1998, pps. 402-408			
	Haemophilia, Vol. 4			
	Ken Nakata et al., Reconstruction of the Lateral Ligar	nents of the Ankle Using Solvent	-dried and Gamma-Irradiated	
	Allogeneic Fascia Lata, May 2000, pps. 579-582			
	Maria Esther Martinez Pardo et al., Clinical Application of Amniotic Membranes on a Patient With Epidermolysis			
	Bullosa, 1999, pps. 68-73, Annals of Transplantation, Vol. 4, No. 3-4			
EXAMINER	D	ATE CONSIDERED		

LIGHT OF PRIOR ART CITED BY		ATTY. DOCKET NO. CI-0012	APPLN. SERIAL NO. 09/960,703		
LIS1 (OF PRIOR ART CITED AND APPLICANT (PTO-1449) (PTO-1449)	APPLICANT Shirley MIEKKA tal.			
		September 24, 2001	GROUP 1744		
OTHER A	RT (Including Author, Title Date Partner				
	Jan Parizek et al., Duraplasty With Pretreated Freeze-Dried Sterilized Human Dura Mater, 1990,				
	pps. 135-143, Sbor. ved. Praci LF UK Hradee Kralove, Vol. 33				
	Jan Parizek et al., Ovine Pericardium: A New Material For Duraplasty, 1996, pps. 508-513,				
	J. Neurosurg., Vol. 84				
	Patel et al., Effect of Gamma Radiation and Ethylene Oxide on Papain, 1979, pps. 81-83, Indian. J. Pharm.				
l'	Sci., Vol. 41, No. 2				
	Z. Mark Plavsic et al., Resistance of Procine Circ	covirus to Gamma Irradiation,	April 2001, pps. 32-35,		
	BioPharm				
-	L.V. Polezhaeu et al., Repair of Cranial Defects	L.V. Polezhaeu et al., Repair of Cranial Defects With Regenerating Bone in Grafting Gamma-Irradiated			
	Bone Filings, pps. 57-60				
	Pollard, The Effect of Ionizing Radiation on Vin	ruses, pps. 65-71			
	Donald J. Prolo et al., Composite Autogeneic Human Cranioplasty: Frozen Skull Supplemental With Fresh Iliac Corticocancellous Bone, December 1984, pps. 846-851, Neurosurgery, Vol. 15, No. 6 Donald J. Prolo et al., Superior Osteogenesis in Transplanted Allogeneic Canine Skull Following Chemical Sterilization, August 1982, pps. 230-242, Clinical Orthopaedics and Related Research, No. 168 Elena Quaglio et al., Copper Converts the Cellular Prion Protein Into a Protease-resistant Species That Is Distinct From the Scrapie Isoform, April 6, 2001, pps. 11432-11438, The Journal of Biological Chemistry, Vol. 276, No. 14				
	T.J. Rasmussen et al., The Effects of 4 Mrad of Gamm				
<u> </u>	Patellar Tendon-Bone Grafts, 1994, pps. 188-197, Th				
	Brian D. Reid, The Sterways Process: A New A	pproach to Inactivating Viruses	s Using Gamma Radiation,		
<u> </u>	1998, pps. 125-130, Biologicals, Vol. 26				
1	S.C. Roe et al., The Effect of Gamma Irradiation	n on a Xenograft Tendon Biopr	rothesis, 1992,		
ļ	pps. 149-154, Clinical Materials, Vol. 9		<u> </u>		
	Robert G. Rohwer, Estimation of Scrapie Nuclei				
	Sensitivity to Ionizing Radiation, March 27, 198				
	Robert G. Rohwer, Scrapie Infectious Agent is V	Virus-like in Size and Susceptif	bility to Inactivation,		
	April 12, 1984, pps. 658-662, Nature, Vol. 308				
	R.G. Rohwer, The Scrapie Agent: A Virus by A	any Other Name, pps. 195-232,	Current Topics in		
	Microbiology and Immunology, Vol. 172				
	Robert G. Rohwer et al., Scrapie-Virus or Viroid, Th				
	System Studies, National Institutes of Neurological and Communicative Disorders and Stroke, National Institutes of Health				
	Robert G. Rohwer, Virus-Like Sensitivity of the	e Scrapie Agent to Heat Inactiv	ation, February 10, 1984,		
	pps. 600-602, Science, Vol. 223				
EXAMINER	[DATE CONSIDERED			

LICTE	OF DRIOR ADT CITEDIA	ATTY. DOCKET NO. CI-0012	APPLN. SERIAL NO. 09/960,703		
LIST	OF PRIOR ART CITED APPLICANT MAR 2 5 2002	APPLICANT Shirley MIEKKA et al.			
	(PTO-1449) MAR 2 5 2002	FILING DATE September 24, 2001	GROUP 1744		
OTHER AR	RT (Including Author, Title: An Retune	nt Pages, Publisher, Place	of Publication, Etc.)		
	Robert Sullivan et al., Inactivation of Thirty Viruses by Gamma Radiation, July 1971, pps. 61-65,				
	Applied Microbiology, Vol. 22, No. 1				
	D. Tylman, Mechanical Character of Liofilized and Sterilized by Gamma-Rays Bone Tissue,				
Ī	1996, pps. 229-234, Chirurgia Narzadow Ruchu I, Ortopedia Polska				
	W. Welch, A Comparative Study of Different Methods of Processing Aortic Homografts, 1969,				
[pps. 746-749, Thorax, Vol. 24				
	J.M. White et al., Sterilization of Teeth by Gamma Radiation, September 1994,				
 	pps. 1560-1567, J. Dent. Res., Vol. 73, No. 9				
	Boon-Seng Wong et al., Copper Refolding of Prior Protein, 2000, pps. 1217-1224, Biochemical and				
	Biophysical Research Communications, Vol. 276				
	Boon-Seng Wong et al., Differential Contribution	on of Superoxide Dismutase Ac	tivity by Prior Protein in		
ľ	Vivo, 2000, pps. 136-139, Biochemical and Bio				
	Boon-Seng Wong et al., Prion Disease: A Loss		•		
	and Biophysical Research Communications, Vo				
	D.E. Wyatt et al., Is There Life After Irradiation		ical Contaminants, June		
<u> </u>	1993, pps. 34-39, BioPharm				
	Qi Zhang et al., Ethylene Oxide Does Not Extinguish the Osteoinductive Capacity of Demineralized Bone,				
1	1997, pps. 104-108, Acta Orthop Scand, Vol. 68, No. 2				
	Yongxing Zhang et al., A Comprehensive Study of Physical Parameters, Biomechanical Properties and Statistical Correlations of Iliac Crest Bone Wedges Used in Spinal Fusion Surgery, 1994, pps. 304-308,				
	Spine, Vol. 19, No. 3				
	License Amendment and procedures for Gamma	a Irradiation of Blood Products,	June 22, 1993, pps. 1-18,		
	Dept. of Health & Human Services, Food and Drug Administration				
	M.F. Alladine et al., γ-Radiation Damage to Starr-Edwards Valves, March 16, 1998, pp. 68, The Lancet,				
	Letters to the Editor				
	Ch. Baquey et al., Radiosterilization of Albumin	nated Polyester Prostheses, May	y 1987, pps. 185-189,		
	Biomaterials, Vol. 8				
7.5	Edward H. Bedrossian, Jr., HIV and Banked Fa	scia Lata, 1991, pps. 284-288,	Ophthalmic Plastic and		
	Reconstructive Surgery, Vol. 7, No. 4				
	Liu Bingci, Mouse Antibody Response Following Repetitive Injections of Gamma-Irradiated Human				
	Placenta Collagen, June 1994, pps. 100-103, Chinese Medical Sciences Journal, Vol. 9, No 2				
	A.A. Belov et al., The Influence of γ-Radiation on Enzyme Activity of Collalitin in the Process of Storage,				
	12/07/89, pps. 519-521, All-Union Research Institute of Textile and Haberdashery Industry, Moscow				
	R.G. Burwell, The Fate of Freeze-Dried Bone Allografts, June 1976, pps. 95-111, Transplantation				
	Proceedings, Vol. VII, No. 2, Supplement 1				
EXAMINER		DATE CONSIDERED			



ATTY. DOCKET NO. APPLN. SERIAL NO. CI-0012 09/960,703 LIST OF PRIOR ART CITEOUR **APPLICANT APPLICANT** Shirley MIEKKA et al. FILING DATE **GROUP** (PTO-1449) Septemb r 24, 2001 1744 OTHER ART (Including Author, Tith Conference Pages, Publisher, Place of Publication, Etc.) L. Callegaro et al., Hollow Fiber Immobilized L-Asparaginase: In Vivo and In Vitro Immunological Studies, 1983, pps. 91-96, The International Journal of Artificial Organs, Vol. 6, No. 2 G. Campalani et al., Aortic Valve Replacement With Frozen Irradiated Homografts, 1989, pps. 558-561, Eur. J. Cardio-thoracic Surgery, Vol. 3

 pps. 556-561, Eur. 5. Cardio-moracic surgery, vol. 5
David T. Cheung et al., The Effect of γ-Irradiation on Collagen Molecules, Isolated α-chains, and
 Crosslinked Native Fibers, 1990, pps. 581-589, Journal of Biomedical Materials Research, Vol. 24
David J. Cohen et al., The Fate of Aortic Valve Homografts 12 to 17 Years After Implantation, March
 1988, pps. 482-484, Chest, Vol. 93, No. 3
A.G. Churchalin et al., Clinical Immunosorbents Basing On Space-Network Polymers, 1998, pps.
 1524-1529, All Union Research Institute of Chemical Reagents and Chemicals of Special Purity, Moscow
P. De Deyne et al., Some Effects of Gamma Irradiation on Patellar Tendon Allografts, 1991, pps. 51-62,
 Connective Tissue Research, Vol. 27
R.I. Vaida et al., Structural-Functional Peculiarities of Myocardial Capillaries After Resection of the Lungs,
10/21/86, pps. 68-73
 R. Guidoin et al., A Compound Arterial Prosthesis: The Importance of the Sterilization Procedure on the
 Healing and Stability of Albuminated Polyester Grafts, March 1985, pps. 122-128, Biomaterials, Vol. 6
Ph. Hernigou et al., Radiation Sterilization of Bone and the HIV Virus, 1993, pps. 445-451, Revue de
Chirurgie Orthopedique, Vol. 79
 Hsing-Wen Sung et al., Effects of Various Chemical Sterilization Methods on the Crosslinking and
and Enzymatic Degradation Characteristics of an Epoxy-Fixed Biological Tissue, December 1996, pps. 376-383, Sterilization of Biological Tissues
 James R. Malm et al., An Evaluation of Aortic Valve Homografts Sterilized by Electron Beam Energy,
October 1967, pps. 471-477, Journal of Thoracic and Cardiovascular Surgery, Vol. 54, No. 4
 James R. Malm et al., Results of Aortic Valve Replacement Utilizing Irradiated Valve Homografts, pps.
740-747, Annals New York Academy of Sciences
W. Oh et al., Mitral Valve Replacement With Preserved Cadaveric Aortic Homografts, May 1973, pps.
 712-721, The Journal of Thoracic and Cardiovascular Surgery, Vol. 65, No. 5
 K. Pietrucha, New Collagen Implant As Dural Substitute, April 1991, pps. 320-323, Biomaterials, Vol. 12

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

EXAMINER

DATE CONSIDERED

	D DV	ATTY. DOCKET NO. CI-0012	APPLN. SERIAL NO. 09/960,703	
TIST OF PRIOR ART CITE	DRI	APPLICANT	·	
APPLICANT (PTO-1449)		Shirl y MIEKKA et al.		
MAR 25 COTTO 1440)	•	FILING DATE	GROUP	
<u> </u>		September 24, 2001	1744	
(Including Author, Title, L				
Maria Raptopoulou-Gigi et al., A	ntimicrobial Pro	oteins in Sterilised Human Mil	k, January 1, 1977,	
pps. 12-14, British Medical Journ				
Edward A. Rittenhouse et al., Ste				
	1-5, Aortic Valve Grafts for Transplantation, Archives of Surgery, Vol. 101, No. 1 H. Sato et al., Sterilization of Therapeutic Immunoadsorbents by Ionizing Radiation,			
H. Sato et al., Sterilization of The				
1986, pps. 131-136, The Internat				
Richard A. Smith et al., Gamma I	rradiation of H	IV-1, 2001, pps. 815-819, Jour	nal of Orthopaedic	
Research, Vol. 19	<u></u>			
Barbara Lüssi-Schlatter et al., Die	e Antimikrobiel	le Behandlung von Peroralen I	Enzympräparaten mit	
Gamma-Strahlen, Pharmazeutisch Galenische Abteilung	Gamma-Strahlen, Pharmazeutisches Institut der Eidgenössischen Technischen Hochschule Zürich			
Martindale's Extra Pharmacopoed	Martindale's Extra Pharmacopoecia, Glucose p. 1265; prior art			
The Merck Index, Eleventh Editi	on Glucose pp.	4353-4354, prior art		
G.L. Moore et al., Effects of 400	0 Rad. Irradiatio	on on the In Vitro Storage Prop	perties of packed Red Cells,	
Nov-Dec 1985, pps. 583-585, Fin	nal Rept., Pub. I	n Transfusion, Vol. 25, No 6 (Abstract)	
Shcheglova et al., The Effect of t	he Power of Ga	mma-Radiation on the Radiation	on Dose in the	
Sterilization of Drugs, 1984, pps.	Sterilization of Drugs, 1984, pps. 730-732, Khim-Farm Zh, Vol. 18, No. 6 (Abstract)			
G.A. Yarygina, Dose Rate Effect	on Survival of	Microorganisms Used As Test	-Cultures in Radiation	
Sterilization of Medical Products	s, 1973, pps. 32-	39, Radiats. Tekh., No. 9 (Abs	stract)	
	·			
		<u> </u>		
				
EXAMINER	0	ATE CONSIDERED		